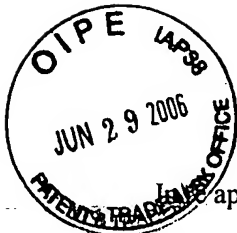


JPW

0590



PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

International application of

Docket No: Q90951

Hideaki SHIMADA, et al.

Appln. No.: 10/554,026

Group Art Unit: Unassigned

Confirmation No.: 1874

Examiner: Unassigned

Filed: October 21, 2005

For: APOPTOSIS-INDUCING AGENT AND METHOD FOR INDUCING APOPTOSIS

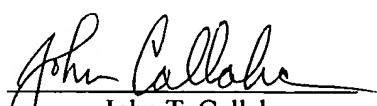
**SUBMISSION OF INTERNATIONAL PRELIMINARY
EXAMINATION REPORT (IPER)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

For the Examiner's convenience, enclosed herewith is a copy of the International Preliminary Examination Report (IPER). It is noted that all of the references identified in the IPER were previously listed on a PTO/SB/08 A & B when a copy of the International Search Report was submitted on October 21, 2005.

Respectfully submitted,


John T. Callahan
Registration No. 32,607

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: June 29, 2006

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF TRANSMITTAL
OF COPIES OF TRANSLATION
OF THE INTERNATIONAL PRELIMINARY REPORT
ON PATENTABILITY
(CHAPTER I OR CHAPTER II
OF THE PATENT COOPERATION TREATY)
(PCT Rules 44bis.3(c) and 72.2)

To:

HIRAKI, Yusuke
Kamiya-cho MT Building, 19F, 3-20
Toranomon 4-chome
Minato-ku Tokyo 105-0001
JAPON



Date of mailing (day/month/year) 09 March 2006 (09.03.2006)	IMPORTANT NOTIFICATION International filing date (day/month/year) 30 March 2004 (30.03.2004)
Applicant's or agent's file reference PH-2082-PCT	
International application No. PCT/JP2004/004516	
Applicant JAPAN SCIENCE AND TECHNOLOGY AGENCY et al	

1. Transmittal of the translation to the applicant.



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter I).



The International Bureau transmits herewith a copy of the English translation of the international preliminary report on patentability (Chapter II).

2. Transmittal of the copy of the translation to the designated or elected Offices.

The International Bureau notifies the applicant that copies of that translation have been transmitted to the following designated or elected Offices requiring such translation:

None

The following designated or elected Offices, having waived the requirement for such a transmittal at this time, will receive copies of that translation from the International Bureau only upon their request:

AE, AG, AL, AM, AP, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EA, EC, EE, EG, EP, ES, FI, GB, GD, GE, GH, GM, GR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OA, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

3. Reminder regarding translation into (one of) the official language(s) of the elected Office(s).

The applicant is reminded that, where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary report on patentability (Chapter II).

It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned within the applicable time limit (Rule 74.1). See Volume II of the PCT Applicant's Guide for further details.

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Authorized officer

Yoshiko Kuwahara

Facsimile No.+41 22 740 14 35

Facsimile No.+41 22 338 90 90

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY (Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference PH-2082-PCT	FOR FURTHER ACTION	See item 4 below
International application No. PCT/JP2004/004516	International filing date (<i>day/month/year</i>) 30 March 2004 (30.03.2004)	Priority date (<i>day/month/year</i>) 21 April 2003 (21.04.2003)
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237		
Applicant JAPAN SCIENCE AND TECHNOLOGY AGENCY		

1.	This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).																								
2.	This REPORT consists of a total of 7 sheets, including this cover sheet. In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.																								
3.	<p>This report contains indications relating to the following items:</p> <table style="width: 100%;"> <tr> <td style="width: 10%; text-align: center;"><input checked="" type="checkbox"/></td> <td style="width: 30%;">Box No. I</td> <td style="width: 80%;">Basis of the report</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. II</td> <td>Priority</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. III</td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. IV</td> <td>Lack of unity of invention</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. V</td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VI</td> <td>Certain documents cited</td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td>Box No. VII</td> <td>Certain defects in the international application</td> </tr> <tr> <td style="text-align: center;"><input checked="" type="checkbox"/></td> <td>Box No. VII</td> <td>Certain observations on the international application</td> </tr> </table>	<input checked="" type="checkbox"/>	Box No. I	Basis of the report	<input type="checkbox"/>	Box No. II	Priority	<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	<input type="checkbox"/>	Box No. IV	Lack of unity of invention	<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited	<input type="checkbox"/>	Box No. VII	Certain defects in the international application	<input checked="" type="checkbox"/>	Box No. VII	Certain observations on the international application
<input checked="" type="checkbox"/>	Box No. I	Basis of the report																							
<input type="checkbox"/>	Box No. II	Priority																							
<input checked="" type="checkbox"/>	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																							
<input type="checkbox"/>	Box No. IV	Lack of unity of invention																							
<input checked="" type="checkbox"/>	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																							
<input checked="" type="checkbox"/>	Box No. VI	Certain documents cited																							
<input type="checkbox"/>	Box No. VII	Certain defects in the international application																							
<input checked="" type="checkbox"/>	Box No. VII	Certain observations on the international application																							
4.	The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).																								

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Date of issuance of this report 02 March 2006 (02.03.2006)
Facsimile No. +41 22 740 14 35	Authorized officer <div style="text-align: center; font-weight: bold;">Yoshiko Kuwahara</div>
Telephone No. +41 22 338 90 90	

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

Translation

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

To:

Date of mailing
(day/month/year)

Applicant's or agent's file reference

PH-2082-PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.

PCT/JP2004/004516

International filing date (day/month/year)

30.03.2004

Priority date (day/month/year)

21.04.2003

International Patent Classification (IPC) or both national classification and IPC

Applicant

JAPAN SCIENCE AND TECHNOLOGY AGENCY

1. This opinion contains indications relating to the following items:

- | | | |
|-------------------------------------|--------------|--|
| <input checked="" type="checkbox"/> | Box No. I | Basis of the opinion |
| <input type="checkbox"/> | Box No. II | Priority |
| <input checked="" type="checkbox"/> | Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability |
| <input type="checkbox"/> | Box No. IV | Lack of unity of invention |
| <input checked="" type="checkbox"/> | Box No. V | Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input checked="" type="checkbox"/> | Box No. VI | Certain documents cited |
| <input type="checkbox"/> | Box No. VII | Certain defects in the international application |
| <input checked="" type="checkbox"/> | Box No. VIII | Certain observations on the international application |

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/JP

Authorized officer

Facsimile No.

Telephone No.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/004516

Box No. 1 Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rule 12.3 and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☒ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☒ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☒ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/004516

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application

☒ claims Nos. 8-14

because:

☒ the said international application, or the said claims Nos. 8-14
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 8-14 relate to methods for treatment of the human body by therapy.

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. _____
are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. _____ are so inadequately supported
by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claims Nos. 8-14

☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:

the written form

☐ has not been furnished

☐ does not comply with the standard

the computer readable form

☐ has not been furnished

☐ does not comply with the standard

☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions.

☐ See Supplemental Box for further details.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/004516

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 1-7

YES

Claims

NO

Inventive step (IS)

Claims 1-7

YES

Claims

NO

Industrial applicability (IA)

Claims 1-7

YES

Claims

NO

2. Citations and explanations:

Claims 1-7

Document 1: (J. Liu, et al.), Mol Cell, February 2000, 5 (2): 331-341

Document 2: (J. Liu, et al.), Cell, 9 February, 2001 (09.02.01), 104 (3): 353-363

Document 3: (L. He, et al.), EMBO J., 1 March, 2000 (01.03.00), 19 (5): 1034-1044

None of the documents cited in the ISR describes or suggests that FIR (FUSE binding protein interacting repressor) has an effect of inducing apoptosis.

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/004516

Box No. VI Certain documents cited

1. Certain published documents (Rule 43bis.1 and 70.10)

Application No. Patent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
WO 2004/018679 A1 [E, X]	04.03.2004	22.08.2003	23.08.2002
WO 2004/027061 A1 [E, Y]	01.04.2004	16.09.2003	17.09.2002

2. Non-written disclosures (Rule 43bis.1 and 70.9)

Kind of non-written disclosure

Date of non-written disclosure
(day/month/year)

Date of written disclosure
referring to non-written disclosure
(day/month/year)

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2004/004516

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

Claims 1, 3 and 5-7

The subject matters of claims 1, 3 and 5-7 relate to an apoptosis-inducing agent having as the active ingredient a protein defined by a desired property as "interacts with FUSE binding proteins". Claims 1, 3 and 5-7 encompass all the proteins that have such property, however, only a limited part of the claimed proteins are disclosed in the sense of PCT Article 5. Therefore, the claims are not supported by the disclosure in the specification in the sense of PCT Article 6.

Even with the common technical knowledge prevailing at the time of filing of the present application, it would have been impossible to define a range of proteins that "interact with FUSE binding proteins". Accordingly, claims 1, 3 and 5-7 do not satisfy the requirement of clarity according to the provisions of PCT Article 6.